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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/542,445      | 04/04/2000  | Mark A. Staples      | BEH-7354A-Div       | 5919             |

7590 04/05/2002

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EXAMINER

DEVI, SARVAMANGALA J N

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1645     | 12           |

DATE MAILED: 04/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                       |                                   |                         |   |
|------------------------------|--------------------------------------|---------------------------------------|-----------------------------------|-------------------------|---|
| <b>Office Action Summary</b> | Application No.<br><b>09/542,445</b> | Applicant(s)<br><b>Staples et al.</b> | Examiner<br><b>S. Devi, Ph.D.</b> | Art Unit<br><b>1645</b> |  |
|                              |                                      |                                       |                                   |                         |   |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)  Responsive to communication(s) filed on Jan 2, 2002

2a)  This action is **FINAL**.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4)  Claim(s) 1-3  is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_  is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_  is/are allowed.

6)  Claim(s) 1-3  is/are rejected.

7)  Claim(s) \_\_\_\_\_  is/are objected to.

8)  Claims \_\_\_\_\_  are subject to restriction and/or election requirement.

**Application Papers**

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_  is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15)  Notice of References Cited (PTO-892)      18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      20)  Other: \_\_\_\_\_

**DETAILED ACTION**

**Applicants' Amendment**

1) Acknowledgment is made of Applicants' amendment filed 06/07/01 (paper no. 7) in response to the restriction requirement mailed 04/24/01 (paper no. 4).

**Status of Claims**

2) Claims 4-39 have been canceled via the amendment filed 06/07/01.

Claims 1-3 are pending and are under examination.

**Prior Citation of Title 35 Sections**

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

**Prior Citation of References**

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

**Objection(s) Withdrawn**

5) The objection to the abstract made in paragraph 5 of the Office Action mailed 09/04/01 (paper no. 9) is withdrawn in light of Applicants' amendment to the abstract.

6) The objection to the specification made in paragraph 7(a) of the Office Action mailed 09/04/01 (paper no. 9) is withdrawn in light of Applicants' amendment to the specification.

**Objection(s) Maintained**

7) The objection to the specification made in paragraph 7(b) of the Office Action mailed 09/04/01 (paper no. 9) is maintained for reasons set forth therein. Applicants request that amendments to the trademark recitations be done via an Examiner's amendment after the indication allowable subject matter.

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**Rejection(s) Maintained**

8) The rejection of claims 1-3 made in paragraph 8(a) of the Office Action mailed 09/04/01 (paper no. 9) under the judicially created doctrine of obviousness-type double patenting over claims 1-4 of the US patent 6,171,801, is maintained for reasons set forth therein. Applicants

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assure the Office that they will file a terminal disclaimer once the claimed deemed allowable.

9) The rejection of claims 1-3 made in paragraph 8(b) of the Office Action mailed 09/04/01 (paper no. 9) under the judicially created doctrine of obviousness-type double patenting over claims 1, 2, 4, 5, 10, 11, 26 and 27 of the patent, US 6,159,698, is maintained for reasons set forth therein. Applicants assure the Office that they will file a terminal disclaimer once the claims are deemed allowable.

**Rejection(s) Withdrawn**

10) The rejection of claims 1-3 made in paragraph 10 of the Office Action mailed 09/04/01 (paper no. 9) under 35 U.S.C § 102(e) as being anticipated by Khanna *et al.* (US 4,798,804), is withdrawn in light of Applicants' amendment to the base claim.

**New Rejection(s)**

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments to the claims and/or the base claim.

**Rejection(s) under 35 U.S.C. § 103**

11) Claims 1-3 are rejected under 35 U.S.C § 103(a) as being unpatentable over Nishijo *et al.* (*Chem. Pharm. Bull.* 33: 2648-2653, 1985, already of record) or Kaufman *et al.* (CA 2,014,233 - Applicants' IDS) in view of Neumann *et al.* (US 4,559,291, already of record) or Khanna *et al.* (US 4,798,804, already of record).

Nishijo *et al.* teach a method of releasing a ligand from a complex formed with an endogenous protein, such as serum albumin, by using benzoic acid. Benzoic acid is taught to release the ligand by competitive interaction with serum albumin (see abstract).

Kaufman *et al.* teach a method of releasing an acidic ligand from a complex with endogenous proteins, for example serum albumin, comprising contacting the sample (medium) suspected of containing the complex with an effective amount of a releasing agent (see page 5 and abstract). The releasing agent when added to an endogenous protein-containing sample in excess competes with the analyte for non-specific binding sites present on proteins such that non-specific binding sites are effectively filled with the releasing agent and "the analyte of interest" is unable to bind to the endogenous proteins and "is now free in solution and available to be assayed (see pages 3 and 4). Various releasing agents that are known in the art and have been

employed in serum assays and urine assays are disclosed on pages 4 and 5. One of the alternative releasing agents taught, along with salicylate or ANS, is benzoic acid (see pages 4, 5, 1 and claims 1 and 11). The contacting of the sample with the releasing agent is performed in a single step.

Nishijo *et al.* or Kaufman *et al.* do not teach the use of the specific benzoic acid species or derivative recited in the instant claims.

However, Neumann *et al.* teach the specific use of *o*-methoxybenzoic acid for releasing a ligand from a complex (see Table V and column 5, last paragraph).

Khanna *et al.* teach a method for releasing a ligand from a complex comprising contacting a sample (i.e., medium) suspected of containing the complex with an effective amount of a releasing agent. A preferred releasing agent is methoxybenzoic acid (see the abstract and column 3, lines 35-57).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace Nishijo's or Kaufman's generic benzoic acid releasing agent with Neumann's or Khanna's specific benzoic acid derivative to produce the method of the instant invention, with a reasonable expectation of success. Substitution of a generic benzoic acid releasing agent with an art-known specific benzoic acid derivative or species would have been well within the realm of routine experimentation, since the latter derivative or species is already taught by Neumann *et al.* or Khanna *et al.* to serve as a releasing agent.

Claims 1-3 are *prima facie* obvious over the prior art of record.

#### Remarks

- 12) Claims 1-3 stand rejected.
- 13) The Applicants' amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**14)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9306.

**15)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 2002

*SD*  
S. DEVI, PH.D.  
PRIMARY EXAMINER